This proceeding has been assigned to the office of Administrative Law Judges. Hearing in this matter, if any is held, shall commence within the time limitations prescribed in 46 CFR 502.61, and only after consideration has been given by the parties and the presiding officer to the use of alternative forms of dispute resolution. The hearing shall include oral testimony and cross-examination in the discretion of the prescribing officer only upon proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record. Pursuant to the further terms of 46 CFR 502.61, the initial decision of the presiding officer in this proceeding shall be issued by October 19, 2000, and the final decision of the Commission shall be issued by February 16, 2001.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 99–27869 Filed 10–25–99; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 11:00 a.m., Monday, November 1, 1999.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Lynn S. Fox, Assistant to the Board; 202–452–3204.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at http://www.federalreserve.gov for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: October 22, 1999.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 99–28098 Filed 10–22–99; 3:53 pm]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4396]

Draft Guidance for Industry on Financial Disclosure by Clinical Investigators; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Financial Disclosure by Clinical Investigators.'' This draft guidance provides clarification, and responds to questions, concerning implementation of the final rule issued by FDA requiring anyone who submits a marketing application for any drug, biologic, or device to submit certain information concerning the compensation to, and financial interests of, any clinical investigator conducting clinical studies covered by the final rule.

DATES: Submit written comments concerning this draft guidance by December 27, 1999.

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Financial Disclosure by Clinical Investigators'' to Mary C. Gross, Office of International and Constituency Relations (HF–24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20856. Send a self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 10–61, Rockville, MD 20852. See the **Supplementary Information** section of this document for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Mary C. Gross, Office of International and Constituency Relations (HF–24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20856, 301–827–3450, FAX 301–827–1335.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Financial Disclosure by Clinical Investigators.'' This draft guidance is intended to provide clarification concerning implementation of the final rule issued by FDA requiring anyone who submits a marketing application for any drug, biologic, or device to submit certain information concerning the compensation to, and financial interests of, any clinical investigator conducting clinical studies covered by the final rule. The requirements of the final rule took effect on February 2, 1999.

The agency's regulations on financial disclosure by clinical investigators require that financial interests and arrangements of clinical investigators that could affect the reliability of data submitted to FDA are identified and disclosed by the applicant. This requirement applies to any clinical study submitted in a marketing application that the applicant or FDA relies on to establish that the product is effective and any study in which a single investigator makes a significant contribution to the demonstration of safety. Applicants are required to certify to the absence of certain financial interests of clinical investigators or to disclose those financial interests. If the applicant does not include a certification and/or disclosure or does not certify that it was not possible to obtain the information, the agency may refuse to file the application.

The agency has received many questions concerning implementation of this final rule and has issued this draft guidance in the form of questions and answers in an effort to respond to these questions. FDA wishes to emphasize its commitment to work with sponsors as they begin their efforts to comply with the provisions of the rule.

II. Electronic Access

Copies of this guidance are available on the Internet. The guidance is located at www.fda.gov/oc/guidance/financialdis.html.

III. Comments

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by December 27, 1999, to ensure adequate consideration in preparation of the final